510(k) Summary

APR 19 2013

April 18, 2013

Applicant:

Tecnología y Diseño Industrial, S.A.P.I. de C.V.
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Trade Name:	Newfix® External Fixation System
Common Name:	External Fixation System
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Classification Panel:	Orthopedic

1.0 DEVICE SUMMARY

The Tecnología y Diseño Industrial, S.A. de C.V. Newfix® External Fixation System consists of various components including fixators, clamps, bars, distractors, carbon fiber rod, and stainless steel rods for use in orthopedic and trauma treatments.

1.1 Classification Information

Table SE1: Device Classification

Classification or descriptor	Name or designation
Common Name	External Fixation System
Device Trade Name	Newfix® External Fixation System
Device Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Device Classification	Class II
Reviewing Panel	Orthopedic
Regulation Number	21 CFR 888.3030
Product Code	KTT

2.0 PREDICATE DEVICES

The Newfix® External Fixation System is substantially equivalent to the following predicate products.

Newfix systems, devices and components – predicate associations

Added system devices or component	Manufacturer and Product	Cleared Predicate Product
Radiolucent Wrist Fixator, Ankle Clamp, Pelvic Fixator (T Clamp for Pelvic Fixator and Straight Clamp for Pelvic Fixator)	**Orthofix Dynamic Axial Fixation System** (primary) EBI® XFIX® DFS and EBI® XFIX® (*Access Pelvic Fixator*)	**k955848**, K013540, K012024, K031919, K953406 K040935
Lengthener(Elongator) Systems	EBI® (*Biomet® Carbon Rail Deformity System*) Orthofix Adult Limb Reconstruction System	K991941, K000083, K010437, K021031, K033635, k081244

3.0 INTENDED USE AND INDICATIONS FOR USE

Indications for Use:

The Newfix® External Fixation System, consisting of axial fixators and frame components, is indicated for stabilization of open and/or unstable fractures where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting. NEWFIX® External Fixation System is intended for the fixation and for temporary or extended stabilization in cases such as: open fractures, closed fractures, poly-trauma fractures, supplement in the stabilization of minimal fixations in intra and extra articular fractures.

The Newfix® External Fixation System lengthening components (rail systems) are unilateral external fixation devices and components intended for use in adults and pediatrics in the treatment of bone conditions including leg lengthening (osteotomies), arthrodesis, fracture fixation, and other bone conditions amendable to treatment by use of the external fixation modality.

Intended Purpose

NEWFIX® External Fixation System is intended for the fixation and for temporary or extended stabilization in cases such as: Exposed Fractures, Fractures of complex traces, Poly-fractures, Supplement in the stabilization of minimal fixations in intra and extra articular fractures.

The lengthening components are intended for fracture and/or deformities correction, and for diaphysary bone recovery.

4.0 DEVICE DESCRIPTIONS

4.1 TDI's Newfix® External Fixation System (Newfix External Fixation System k101338 and

Newfix Screws, Wires and Pins k101254 and this submission under review) consists of bone screws, pins and wires and external fixation components and lengthening systems. The System is utilized in the following manner: bone screws are inserted through the patient's skin and soft tissue and into the bone. The fixator frame of the Newfix® External Fixation System is attached to the shanks of the bone screws. The intended use and product technology of this submission have not changed from the earlier cleared submissions.

4.2 The present submission adds axial and pelvic fixation devices (including radiolucent wrist fixator), straight and angled clamps and rail lengthening transport systems.

4.3 The Newfix® External Fixation System is supplied non sterile and is intended for single patient use. None of the components of the Newfix System are reusable. The Newfix® External Fixation System includes instruments and accessory devices necessary for its use.

5.0 COMPARISON OF DEVICE UNDER REVIEW AND ITS PREDICATES

Comparison Element	TDI Newfix ®External Fixation System	Orthofix Modulsystem Dynamic Axial Fixation System and Adult Limb Reconstruction System K955848	Biomet EBI® XFIX® DFS Access K953406 K013540, k081244
Manufacturer	Tecnología y Diseño Industrial S.A.P.I. de C.V.	Orthofix	Biomet Trauma
Indication for/ Intended Use	The Newfix® External Fixation System, consisting of axial fixators and frame components, is indicated for stabilization of open and/or unstable fractures where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting. NEWFIX® External Fixation System is intended for the fixation and for temporary or extended stabilization in cases such as: open fractures, closed fractures, poly-trauma fractures, supplement in the stabilization of minimal fixations in intra and extra articular fractures. The Newfix® External Fixation System lengthening components (rail systems) are unilateral external fixation devices and components intended for use in adults and pediatrics in the treatment of bone conditions including leg lengthening (osteotomies), arthrodesis, fracture fixation, and other bone conditions amendable to treatment by use of the external fixation modality.	Orthofix Dynamic Axial Fixation System is a unilateral external fixation device, which is intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation and other bone conditions amenable to treatment by use of the external fixation modality."	Unilateral external fixation device intended for use in children and adults in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amendable to treatment by use of the external fixation modality. For the XFIX® DFS® Rail System the indications are unilateral external fixation device intended for use in children and adults in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, acute or gradual correction and other bone conditions amendable to treatment by use of the external fixation modality

Comparison Element	**TDI Newfix ®External Fixation System**	**Orthofix Modulsystem Dynamic Axial Fixation System and Adult Limb Reconstruction System K955848**	**Biomet EBI® XFIX® DFS Access K953406 K013540, k012024**
Materials	Aluminum 6061-T6 Stainless Steel 17-4PH (AISI 630), Stainless steel 304 Stainless steel 316LS Titanium alloys Carbon fiber	Aluminum, Stainless steel, Composite materials	Aluminum, Stainless steel, Titanium alloy, and Carbon fiber
Duration of Use	Greater than 30 days	Greater than 30 days	Greater than 30 days
Sterile or non sterile	Non Sterile requiring sterilization	Non Sterile requiring sterilization	Non Sterile requiring sterilization
Reuse Capability	Single Use	Single Use	Single Use

5.1 Performance Tests

5.1.1 Performance tests were conducted to validate the locking mechanism of the

Newfix External Fixation System against various components of the Orthofix predicate devices.

TDI Products tested:

E0300104 Lateral Cylinder for Pins (Straight Clamp).

E0600201 T-Shaped Clamp.

E0600301 Angled Clamp.

E0600401 Ankle Clamp.

E0900104/5 RadioLucent Wrist Axial Fixator Clamp.

Predicate Devices tested:

Orthofix ProCallus Fixator Straight Clamp

Orthofix T-Shaped Clamp

Orthofix Ankle Clamp

Orthofix RadioLucent Wrist Fixator Clamp

Materials used:

Ø6mm (0.236in) and Ø4mm (0.157in) series 316 stainless steel rods.

Ø6mm (0.236in) and Ø4mm (0.157in) series 316 stainless steel rods with a hexagonal nut for torque tests.

Socket Set Screws Flat Point ISO 4026 M8x1.25.

Measuring tools:

TDI.QC.023 PTS Analog push pull gauge SKN-5

S/N3409090760 TDI.QC.027 Dial torque wrench 6178A S/N

0207801708

Referenced Standards

ASTM F 1541 Standard Specification and Test Methods for External Skeletal Fixation Devices.

ASTM E 4 Practices for Force Verification of Testing Machines

5.1.2 TDI performance testing for the rail system for lengthening (dynamization clamp), multiplanar clamp, pelvic fixator and links, radiolucent wrist fixator and radiolucent ankle clamp (as a fixator, clamp and for PEKK material) has been completed successfully.

Performance testing supporting new indications for lengthening and arthrodesis are included in the reports.

Performance testing has evaluated the performance of these components in order to demonstrate that they are as safe and as effective as legally marketed predicate devices.

Testing has been conducted using a worst case construct as provided in ASTM F1541using both static and dynamic testing modes.

Testing included Newfix components/systems in comparison against Orthofix systems as legally marketed predicate devices/systems.

5.1.3 Testing to evaluate loosening of system components including the dynamization clamp, mulitplanar clamp, and pelvic links as part of Newfix systems was conducted as part of the Performance Testing. Testing resulted in no observation of loosening of system components.

6.0 CONCLUSION

6.1 Testing per ASTM F 1541 and engineering analysis including component loosening compared to the predicate systems demonstrated equivalency.

6.2 The Newfix External Fixation System is substantially equivalent to the identified predicate systems based on the substantial equivalence of indication for use, design features, operating principles, performance tests and material of composition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Technología y Diseño Industrial, S.A.P.I. de C.V.
% HealthCare Technologies Consultants
Mr. Robert J. Bard
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Letter dated: April 19, 2013

Re: K122210
Trade/Device Name: Newfix® External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: April 10, 2013
Received: April 11, 2013

Dear Mr. Bard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k): 122210

Device Name: Newfix® External Fixation System

The Newfix® External Fixation System, consisting of axial fixators and frame components, is indicated for stabilization of open and/or unstable fractures where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting. NEWFIX® External Fixation System is intended for the fixation and for temporary or extended stabilization in cases such as: open fractures, closed fractures, poly-trauma fractures, supplement in the stabilization of minimal fixations in intra and extra articular fractures.

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Prescription Use X (21 CFR Part 801 Subpart D)	and/or	Over the Counter Use __ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices